Special 510(k)
MRC Systems: ModuLeaf
February 21, 2003

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K030609

MRC Systems GMBH
Hans-Bunte-Str. 10
D-69123 Heidelberg
Germany
Phone: (+49) 6221-13803-00
Fax: (+49) 6221-13803-01

Department of Health and Human Services
Center of Device and Radiological Health
Office of Device Evaluation
Special 510(k) section

510(K) SUMMARY OF SAFETY AND EFFECTIVENESS INFORMATION

as required by section 807.92(c)

Submitter of 510(k):

Company name:	MRC Systems GmbH
Registration number:	9040319
Address:	Hans-Bunte-Str. 10 69123 Heidelberg Germany
Phone:	(+49) 6221-13803-00
Fax:	(+49) 6221-13803-01
Correspondent:	Mark-Aleksi Keller-Reichenbecher Ph.D. Manager Quality Assurance & Regulatory Affairs

Modified Device Name:

Trade/Proprietary Name:	ModuLeaf
Common/Usual Name:	Multileaf Collimator
Classification Name:	Block, Beam Shaping, Radiation Therapy
Classification	21 CFR 892.5710, Class II

Legally Marketed Device(s)

Our device is substantially equivalent to the legally marketed predicate device cited in the table below:

Manufacturer	Device	510(k) #
MRC Systems GmbH	Mini Multileaf Collimator	K011816

Description:
The ModuLeaf is a conformal radiation therapy and radiosurgery device that is mounted to a standard radiation therapy linear accelerator (Linac). The ModuLeaf receives input from

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planning system software that determines the collimator aperture shapes at different gantry positions along the arc around the target area. Radiation is delivered at a constant rate.

The ModuLeaf consists of three parts: (1) the user console, (2) the control cabinet and (3) the collimator mechanism.

The control cabinet with the user console serves as the control station for the operator and is located near the Linac operator console. The control cabinet contains the PC, an interface board and the power supply. The PC consists of a specified configuration of a CPU, motherboard, RAM, VGA board and HDD. It is used as the communication interface between the operator and the planning system software or the record and verify (R&V) system that contains the treatment positioning data. The PC also serves as the master for the control and verification system. The data received from the planning system software or the record and verify (R&V) system is processed and transferred to the micro-controllers on the control and verification boards.

The operator initiates position adjustment at the console or at the record and verify (R&V) system depending on the configuration. When an R&V system is involved the leaf positions are downloaded to the PC. The PC then starts all the micro-controllers simultaneously and retrieves the position of the leaves, comparing the values of the control system with those of the verification system.

The collimator mechanism is fitted to the accessory holder of the Linac gantry. It consists of 80 driving units that position the tungsten leaves via a rack and pinion mechanism. Two independent potentiometers are directly connected with each tungsten leaf to retrieve information on the leaf position, i.e. there are 80 potentiometers for leaf positioning and an additional 80 potentiometers for independent leaf position verification. They serve as feedback for the verification system that checks the correct positioning of the leaves.

Intended use:
The ModuLeaf is a conformal radiation therapy and radiosurgery device that delivers a shaped X-ray beam from a radiation therapy source. The ModuLeaf is attached to a linear accelerator and consists of a series of pairs of tungsten leaves that collimate the radiation delivery to a target based on a treatment plan generated by planning software. The device is used to help the clinician deliver well-defined target volumes of radiation while sparing the surrounding tissues and organs.

Summary of technological considerations:
The MRC Systems, ModuLeaf, is substantially equivalent to the cleared predicate device, Mini Multileaf Collimator, K011816.

Name: Mark-Aleksi Keller-Reichenbecher Ph.D.
Title: Manager
Quality Assurance & Regulatory Affairs
MRC Systems GMBH
Heidelberg, Germany

02 Feb 21
Date

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 17 2003

Joerg Stein, Ph.D.
Managing Director
MRC Systems GMBH
Hans-Bunte-Straβe 10
69123 Heidelberg
GERMANY

Re: K030609
Trade/Device Name: Moduleaf
Regulation Number: 21 CFR 892.5710
Regulation Name: Radiation therapy beam-shaping block
Regulatory Class: II
Product Code: 90 IXI
Dated: February 21, 2003
Received: February 26, 2003

Dear Dr. Stein:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of the letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Applicant: MRC Systems
510(k) Number (if known): K030609
Device Name: ModuLeaf

Indications For Use:

The ModuLeaf is a conformal radiation therapy and radiosurgery device that delivers a shaped X-ray beam from a radiation therapy source. The ModuLeaf is attached to a linear accelerator and consists of a series of pairs of tungsten leaves that collimate the radiation delivery to a target based on a treatment plan generated by planning software. The device is used to help the clinician deliver well-defined target volumes of radiation while sparing the surrounding tissues and organs.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Per 21 CFR 801.109)
(Optional Format 1-2-96)

Prescription Use ✓

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K030609